

Terrestrial Animal Health Standards Commission Report September 2015

CHAPTER 5.3.

OIE PROCEDURES RELEVANT TO THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES OF THE WORLD TRADE ORGANIZATION

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) encourages the Members of the World Trade Organization to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to implement sanitary measures more stringent ~~adopt a higher level of protection than that provided by those in international standards texts~~ if there is a scientific justification ~~or if the level of protection provided by the relevant international texts is considered to be inappropriate~~. In such circumstances, Members are subject to obligations relating to *risk assessment* and to a consistent approach of *risk management*.

~~The SPS Agreement encourages Governments to make a wider use of risk analysis: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual risk involved.~~

The SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, sanitary measures which may, directly or indirectly, affect international trade.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live *animals* and animal products.

Article 5.3.2.

Introduction on the judgement of the equivalence of sanitary measures

The importation of *animals* and animal products involves a degree of *risk* to the animal and human health status of an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made more difficult by differences among the animal health management systems and animal production systems in Member Countries. However, ~~it is now~~ recognised that significantly different ~~animal health and production~~ systems can provide equivalent animal and human health protection for the purposes of *international trade*, ~~with benefits to both the importing country and the exporting country.~~

These recommendations are to assist Member Countries to determine whether *sanitary measures* arising from different ~~animal health and production~~ systems may provide the same level of animal and human health protection. They discuss principles which might be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in determining ~~facilitating a judgement of~~ equivalence. These provisions are applicable whether equivalence applies ~~at the level of~~ to specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or generally.

Article 5.3.3.

General considerations on the judgement of the equivalence of sanitary measures

Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its *animal health status and human health* will be appropriately protected. In most cases, the *risk management* measures adopted ~~drawn up~~ will rely in part on judgements made about the animal health and production system(s) in the *exporting country* and the effectiveness of *sanitary measures* procedures applied ~~undertaken~~ there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be with respect to infrastructure, policies ~~and/or~~ operating procedures, *laboratory* systems, approaches to control of the pests and diseases present, border security and internal movement controls.

~~International recognition of the legitimacy of different approaches to achieving the importing country's appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.~~

Benefits of applying equivalence may include:

- minimising costs associated with international trade by tailoring sanitary measures ~~animal health measures~~ to local circumstances;
- maximising animal health outcomes for a given level of resource input;
- facilitating trade by achieving the required health protection through less trade restrictive sanitary measures; and
- decreased reliance on relatively costly commodity testing and isolation procedures in bilateral or multilateral agreements.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases, infections* and *infestations* ~~pathogenic agents~~. Equivalence may be gained, for example, by enhanced *surveillance* and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above.

To facilitate the judgement of equivalence, Member Countries should base their *sanitary measures* on the standards, and guidelines ~~and recommendations~~ of the OIE.

~~It is essential to apply a scientific~~ Member Countries should use *risk analysis* ~~to the extent practicable in~~ establishing the basis for a judgement of equivalence.

Article
5.3.4.**Prerequisite considerations in a judgement of equivalence**1. Application of risk assessment

~~Application of the discipline of~~ *Risk assessment* provides a structured basis for judging equivalence among different *sanitary measures* as it allows a comparison ~~close examination to be made~~ of the effect of a measure(s) on a particular step(s) in the importation pathway, ~~and the relative~~ with the effects of a proposed alternative measure(s) ~~on the same or related steps~~.

A judgement of equivalence should ~~needs to~~ assess the *sanitary measure* in terms of its effectiveness against ~~regarding~~ the particular *risk* or group of *risks* against which it ~~the~~ measure is designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the importing country.

2. Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising a single component of a measure (e.g. an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for *commodity*), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

Sanitary measures are ~~those~~ described in each disease-specific chapter of the *Terrestrial Code* ~~which are used for reducing risks reduction and are appropriate for particular posed by that diseases, infection or infestation~~. *Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of judging equivalence, *sanitary measures* can be broadly categorised as:

- a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of Veterinary Services ~~national and regional animal health authorities, emergency response organisations~~);
- b) programme design and implementation: including documentation of systems, performance and decision criteria, *laboratory* capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

A sanitary measure(s) proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, such as a method for pathogen inactivation, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's* animal health management systems and animal production system. ~~For example, a judgement of equivalence for a specific sanitary measure at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.~~

Article
5.3.5.

Principles for judgement of equivalence

In conjunction with the above considerations, judgement of the equivalence of *sanitary measures* should be based on application of the following principles:

- 1) an *importing country* has the right to set the level of protection it deems appropriate (~~its ALOP~~) in relation to human and animal life and health in its territory; this ~~ALOP~~ may be expressed in qualitative or quantitative terms;
- 2) the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a *hazard*;
- 3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of providing the same level of protection, in particular, it should consider the existence of specified disease-free zones/regions or compartments;
- 4) the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a judgement of equivalence;
- 5) any *sanitary measure* or combination of *sanitary measures* can be proposed for judgement of equivalence;

- 6) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, to minimise administrative burden, and to facilitate resolution of claims;
- 7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure(s)* proposed as equivalent will provide the same level of protection;
- 8) the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;
- 9) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and in accordance with appropriate *risk assessment* principles;
- 10) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
- 11) the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;
- 12) the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
- 13) to facilitate a judgement of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards, where these exist;
- 14) to allow the judgement of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and
- 15) appropriate technical assistance from an importing country, following a ~~should give positive consideration to a request by an exporting developing country, for appropriate technical assistance that would~~ may facilitate the successful completion of a judgement of equivalence.

Article
5.3.6.

Sequence of steps to be taken in judgement of equivalence

There is no single sequence of steps which must be followed in all judgements of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. Nevertheless, ~~the~~ interactive sequence of steps described below may be useful for assessing any ~~all~~ *sanitary measures* irrespective of their categorisation as infrastructure, programme design ~~and~~ implementation or specific technical requirement components of an animal health management system or ~~and~~ animal production system.

This sequence assumes that the importing country is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Recommended steps are:

- 1) the *exporting country* identifies the measure(s) for which it wishes to propose an alternative ~~measure(s)~~, and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a *hazard(s)*;
- 2) the *importing country* explains the reason for the measure(s), in terms that ~~which~~ would facilitate comparison with an alternative *sanitary measure(s)* and consistent with the principles set out in these provisions;
- 3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure(s)* in a form which facilitates evaluation ~~analysis~~ by an *importing country*;

- 4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
- 5) judgement of equivalence by the *importing country* should takes into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative *sanitary measure(s)* ~~on all relevant hazards~~;
 - c) OIE standards;
 - d) application of ~~solely qualitative frameworks where it is not possible or reasonable to conduct quantitative risk assessment~~;
- 6) the *importing country* notifies the *exporting country* of its judgement and ~~its the underlying~~ reasons within a reasonable period of time. The judgement:
 - a) ~~recognitions~~ uses of the equivalence of the *exporting country's* alternative *sanitary measure(s)*; or
 - b) requests ~~for~~ further information; or
 - c) rejections of the case for equivalence of the alternative *sanitary measure(s)*;
- 7) an attempt should be made to resolve any differences of opinion over judgement of a case, ~~either interim or final~~, by using an agreed mechanism such as to reach consensus (e.g. the OIE informal procedure for dispute mediation), or by referral to an agreed expert (Article 5.3.8.);
- 8) depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal or informal agreement of equivalence ~~agreement~~ giving effect to the judgement ~~or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice~~.

An *importing country* recognising the equivalence of an *exporting country's* alternative *sanitary measure(s)* ~~needs to~~ should ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or a very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent because as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.

Article 5.3.7.

Sequence of steps to be taken in establishing a zone/ or-compartment and having it recognised for international trade purposes

The establishment There is no single sequence of steps which should be followed in establishing of a disease-free zone or a compartment is described in Chapter 4.3 and should be considered by trading partners when establishing sanitary measures for trade. The steps that the Veterinary Services of the importing country and the exporting country choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The Recommended steps are:

1. For zoning
 - a) The *exporting country* identifies a geographical area within its territory, which it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific ~~disease/specific diseases,~~ infection or infestation, based on surveillance.
 - b) The *exporting country* describes in the *biosecurity plan* for the zone the measures ~~which are being, or will be,~~ applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.
 - c) The *exporting country* provides:

- i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;
 - ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.
- d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals* and animal products, taking into account:
- i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the *disease(s)* concerned; and
 - iv) other relevant OIE standards.
- e) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
- i) recognition of the *zone*; or
 - ii) request for further information; or
 - iii) rejection of the area as a *zone* for *international trade* purposes.
- f) An attempt should be made to resolve any differences over recognition of the *zone*, ~~either in the interim or finally~~, by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognising the *zone*.

2. For compartmentalisation

- a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* comprising an animal *subpopulation* contained in one or more *establishments* or other premises operating under common management practices and related to biosecurity. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific disease(s). The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
 - i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
 - ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to such the disease(s) in question.
- c) The *exporting country* describes the *compartment*, in accordance with ~~the recommendations in the Terrestrial Code~~ Chapters 4.3. and 4.4.

- d) The *exporting country* provides:
- i) the above information to the *importing country*, with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
 - ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.
- e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *animals* or ~~and~~ animal products, taking into account:
- i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the disease(s) concerned; and
 - iv) other relevant OIE standards.
- f) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
- i) recognition of the *compartment*; or
 - ii) request for further information; or
 - iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.
- g) An attempt should be made to resolve any differences over recognition of the *compartment*, ~~either in the interim or finally~~, by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognising the *compartment*.
- i) The *Veterinary Authority* of the *exporting country* should promptly inform *importing countries* of any occurrence of a *disease* in respect of which the *compartment* was defined.

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE ~~shall maintain its existing~~ a voluntary in-house mechanisms for assisting Member Countries to resolve differences. In-house procedures ~~that which~~ will apply are that:

- 1) Both parties agree to give the OIE a mandate to assist them in resolving their differences.
- 2) If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
- 3) Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.

- 4) The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
- 5) The expert or experts shall submit a confidential report to the Director General of the OIE, who will transmit it to both parties.

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